Exhibit 15

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/393,768	02/26/2009	Pierre F. Lebreton	18498 (COR)	1333

51957 7590 05/31/2011

ALLERGAN, INC.
2525 DUPONT DRIVE, T2-7H
IRVINE, CA 92612-1599

EXAMINER	
SOROUSH, ALI	
ART UNIT	PAPER NUMBER
1617	

NOTIFICATION DATE	DELIVERY MODE
05/31/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents_ip@allergan.com

Office Action Summary	Application No.	Applicant(s)	
	12/393,768	LEBRETON, PIERRE F.	
	Examiner	Art Unit	
	ALI SOROUSH	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 February 2009* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :02262009, 03092009, 08042009, 11162009, 07212009, 082020009, and 12022010.

DETAILED ACTION

Claim Status

Claims 1-36 are pending.

Claims 26-36 have been newly added by a preliminary amendment filed on 12/16/2009.

Claims 1-36 have been examined.

Claims 1-36 are rejected.

Priority

Priority to applications 60/085956 filed on 08/04/2008, 61/087934 filed on 08/11/2008, and 61/096278 filed on 09/11/2008 is acknowledged.

Information Disclosure Statement

The information disclosure statements (IDSs) submitted on 02/26/2009, 03/09/2009, 08/04/2009, 11/16/2009, 07/21/2010, 08/20/2010, and 12/02/2010 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Drawings

The drawings filed on 02/26/2009 are accepted.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. §101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. §101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. §101.

Claims 1, 9, 10, 11 and 14-19 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 8, 11, 10, 12, 13, 15, 17, 20, 21, and 27 of copending Application No. 12/393884. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claims 1, 9, 10, 11 and 14-19 of this application conflict with claims 1, 8, 10, 12, 13, 15, 17, 20 and 27 of Application No. 12/393884. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence

of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 15 recites the limitation "The method of claim 13" in line 1 and "said adjusted pH" in line 1. There is insufficient antecedent basis for these limitations in the claim.

Claim 16 recites the limitation "The method of claim 13" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 17 recites the limitation "The method of claim 13" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 18 recites the limitation "said alkaline" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 19 recites the limitation " said alkaline " in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claims 20-23 recite the limitation "The method of claim 13" in line 1. There is insufficient antecedent basis for this limitation in the claims.

Claims 21 and 27 recited "at least about". The metes and bounds of the instant claims are not clear as there is no discernable upper limit to the range (MPEP 2173.05(b).

Claims 13, 23 and 25 recited "greater than about". The metes and bounds of the instant claims are not clear as there is no discernable upper limit to the range.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-12, 14-22, 24, and 26-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lebreton (US Patent Application 2006/0194758 A1, Published 08/31/2006) in view of Wang (US Patent Application 2005/0271729 A1, Published 12/08/2005).

For purposes of compact prosecution, claims 15-17 and 20-23 have been interpreted as depending from claim 14.

The claims are directed to a composition comprising hyaluronic acid (HA) component crosslinked with a crosslinking agent such as 1,4-butanediol diglycidyl ether (BDDE) and at least one anesthetic agent such as lidocaine. The claims are further directed to the amount of uncrosslinked (HA) is at least 20%. The claims are further directed to the composition has a degree of crosslinking of less than about 6%, 5%, and/or 2%. The claims are further directed to composition comprises 0.1% to 5.0% of an anesthetic. The claims are further directed to a method of preparing a the composition comprising providing hyaluronic acid (HA) component crosslinked with a crosslinking agent such as 1,4-butanediol diglycidyl ether (BDDE), adjusting the pH to above about 7.2/7.5, and adding a solution containing at least one anesthetic agent such as lidocaine. The claims are further directed to a method wherein HA component is hydrated with an alkaline solution. The claims are further directed to a method wherein the alkaline, uncrosslinked NaHa gel has a pH of greater than about 10. The claims are further directed to a method wherein the HA component is a mixture of low molecular weight HA and high molecular weight HA with at least a weight of about 1 million daltons. The claims are further directed to the molecular weight of the high molecular weight HA component being 2.0 million Dalton or 2.8 million Dalton. The claims are further directed to the molecular weight of the low molecular weight HA component being between 0.3 million Dalton and 0.75 million Dalton. The claims are further

directed to the composition comprising 90% low molecular weight HA component and 10% high molecular weight HA component.

Lebreton teaches a method of forming monohase hydrogel by adding a mixture of sodium hyaluronate (NaHA) fibers to 7.5g of 02.5N NaOH (giving a solution of pH 10 or greater) to hydrate; to this hydrate gel BDDE is added and homogenized; the crosslinked product is neutralized to pH 7.2 with phosphate buffer; the resulting hydrogel is homogenized before being packed into syringes and sterilized in an autoclave (paragraphs 0074, 0076, 0086, 0087, 0090, and 0091). The degree of crosslinking is 6.5% and viscosity is 41 at 1 Hz (approximately 5Hz) (table). The mixture of NaHA fibers are at 90% low molecular weight HA component and 10% high molecular weight having a molecular weight of 10,000 Daltons to 1 million Dalton and HA component having a molecular weight of greater than or equal to 1 million daltons (table and prior art claims 1 and 5). The formulation can be buffered to a pH 6.5 to 7.5 (paragraph 0048). The degree of crosslinking can be adjusted to between 0.5 and 70% (paragraph 0046; limitation of claims 2-8).

Lebreton lacks a teaching wherein the hydrogel further comprises an anesthetic agent such as lidocaine.

Wang teaches the formation of crosslinked hyluronic acid which further comprises preferably an anesthetic such as lidocaine (paragraph 011).

The teachings of Lebreton and Wang are directed to cross-linked HA compositions. Thus, it would have been *prima facie* obvious to one of ordinary skill in

the art at the time of the instant invention to add lidocaine to the hydrogel of Lebreton in order to provide a therapeutic delivery of an anesthetic to the injectable formulation. One would have had a reasonable expection of success since both Lebreton and Wang are directed to crosslinked hyaluronic acid formulations. With regard to the amount of uncrosslinked HA being present is greater than 20%, the preferred embodiment shows 6.5% crosslinking and therefore the remainder (93.5%) would be uncrosslinked. With regard to the degree of crosslinking being about 2%, it would have been obvious to adjust the crosslinking through routine optimization since the instant amount is within the range taught in the prior art. With regard to the concentration of lidocaine present in the hydrogel it would have been obvious to one of ordinary skill in the art at the time of the instant invention to arrive at the instant concentration through routine optimization. With regard to the limitation that the composition is a soft tissue filler, this is an intended use of the composition and therefore not given patentable weight.

Claims 1-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lebreton (US Patent Application 2006/0194758 A1, Published 08/31/2006) in view of Lupo (Hyaluronic Acid Fillers in Facial Rejuvenation, Published 10/18/2006).

The claims are directed to a composition comprising hyaluronic acid (HA) component crosslinked with a crosslinking agent such as 1,4-butanediol diglycidyl ether (BDDE) and at least one anesthetic agent such as lidocaine. The claims are further directed to the amount of uncrosslinked (HA) is at least 20%. The claims are further directed to the composition has a degree of crosslinking of less than about 6%, 5%,

and/or 2%. The claims are further directed to composition comprises 0.1% to 5.0% of an anesthetic. The claims are further directed to a method of preparing a the composition comprising providing hyaluronic acid (HA) component crosslinked with a crosslinking agent such as 1,4-butanediol diglycidyl ether (BDDE), adjusting the pH to above about 7.2/7.5, and adding a solution containing at least one anesthetic agent such as lidocaine. The claims are further directed to a method wherein HA component is hydrated with an alkaline solution. The claims are further directed to a method wherein the alkaline, uncrosslinked NaHa gel has a pH of greater than about 10. The claims are further directed to a method wherein the HA component is a mixture of low molecular weight HA and high molecular weight HA with at least a weight of about 1 million daltons. The claims are further directed to the molecular weight of the high molecular weight HA component being 2.0 million Dalton or 2.8 million Dalton. The claims are further directed to the molecular weight of the low molecular weight HA component being between 0.3 million Dalton and 0.75 million Dalton. The claims are further directed to the composition comprising 90% low molecular weight HA component and 10% high molecular weight HA component. The claims are further directed to the crosslinked HA particles having a particles size of greater than 200μm (microns).

Lebreton teaches a method of forming monohase hydrogel by adding a mixture of sodium hyaluronate (NaHA) fibers to 7.5g of 02.5N NaOH (giving a solution of pH 10 or greater) to hydrate; to this hydrate gel BDDE is added and homogenized; the crosslinked product is neutralized to pH 7.2 with phosphate buffer; the resulting

hydrogel is homogenized before being packed into syringes and sterilized in an autoclave (paragraphs 0074, 0076, 0086, 0087, 0090, and 0091). The degree of crosslinking is 6.5% and viscosity is 41 at 1 Hz (approximately 5Hz) (table). The mixture of NaHA fibers are at 90% low molecular weight HA component and 10% high molecular weight having a molecular weight of 10,000 Daltons to 1 million Dalton and HA component having a molecular weight of greater than or equal to 1 million daltons (table and prior art claims 1 and 5). The formulation can be buffered to a pH 6.5 to 7.5 (paragraph 0048). The degree of crosslinking can be adjusted to between 0.5 and 70% (paragraph 0046).

Lebreton lacks a teaching wherein the hydrogel further comprises lidocaine and further wherein the HA particles are greater then 200 microns.

Lupo teaches HA filler compositions for facial rejuvenation (title). Restylane is a HA filler being crosslinked with BDDE having a mean particle size of 300 microns (table 1). Lupo further teach that lidocaine in facial rejuvenation fillers has anti-bruising benefits (page 125, column 1, lines 1-10).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the instant invention to add lidocaine to the hydrogel of Lebreton in order to provide anti-bruising benefit when the hydrogel composition of Lebreton is utilized for facial rejuvenation. It would have been obvious to one of ordinary skill in the art to use HA particles of 300 microns as taught by Lupo in order to use the composition for facial rejuvenation. One would have expected success since both Lebreton and Lupo are directed to HA fillers that are similar in that they are both hyrdogels of HA crosslinked

with BDDE. With regard to the amount of uncrosslinked HA being present is greater than 20%, the preferred embodiment shows 6.5% crosslinking and therefore the remaineder (93.5%) would be uncrosslinked. With regard to the degree of crosslinking being about 2%, it would have been obvious to adjust the crosslinking through routine optimization since the instant amount is within the range taught in the prior art. With regard to the concentration of lidocaine present in the hydrogel it would have been obvious to one of ordinary skill in the art at the time of the instant invention to arrive at the instant concentration through routine optimization.

Conclusion

Claims 1-36 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALI SOROUSH whose telephone number is (571)272-9925. The examiner can normally be reached on M-F (9am-6pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fereydoun G. Sajjadi can be reached on (571)272-3311. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. S./
Examiner, Art Unit 1617

May 17, 2011

/Fereydoun G Sajjadi/
Supervisory Patent Examiner, Art Unit 1617